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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,108	12/01/2003	Hideki Thoda	245694US0CONT	3217
22850	7590	01/26/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.			EXAMINER	
140 DUKE STREET			JOIKE, MICHELE K	
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			1636	
NOTIFICATION DATE	DELIVERY MODE			
01/26/2009	ELECTRONIC			

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/724,108	<b>Applicant(s)</b> THODA ET AL.
	<b>Examiner</b> MICHELE K. JOIKE	<b>Art Unit</b> 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 29 October 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 14,15,17-21 and 23-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 14,15,17-21 and 23-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

#### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed October 29, 2008. Claims 14, 15, 17-21 and 23-25 are pending and examined. Any rejection of record in the previous Office Action, mailed August 6, 2008 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 15, 17-21 and 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,110,703 (Egel-Matani) in view of the *Schizosaccharomyces pombe* genome database, and in further view of Hombergh et al. This rejection is maintained for reasons of record.

#### ***Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)***

Applicant's arguments filed October 29, 2008 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants have filed a certified English translation of foreign application JP2001-160128, filed May 28, 2001. The JP2001-160128 shows that inventors had reduced to practice a method of constructing *S. pombe* strains by deleting or inactivating one or more genes in that strain for producing a heterologous protein as of May 28, 2001, which is prior to the February 21, 2002 date on which the *S. pombe* database was reportedly published.

Further, as explained previously the role of a certain gene and its effects, when deleted in one yeast are different from a corresponding or similar gene in another yeast species. For example, *S. pombe* has greater than 60 protease genes and the effect of removing those on the production of heterologous proteins would not have been clear to one in this field when the application was filed. As there was no guidance in the art nor expectation of success as to which genes (regardless of whether the sequences were known) could be deleted to enhance heterologous protein production, the claims would not have been obvious.

Applicant's arguments have not been found persuasive for the following reasons.

There is support in JP2001-160128 for only *S. pombe* proteases, SPAC4F8.07c and SPAC4A8.04. The *Schizosaccharomyces pombe* genome database ([www.genedb.org/genedb/pombe/](http://www.genedb.org/genedb/pombe/)) also teaches *S. pombe* proteases, SPAC4F10.02 and SPBC16G5.09, for example.

There was guidance in the art and an expectation of success for deleting genes that encode proteases that could be deleted to enhance heterologous protein production. Egel-Matani et al teach a method of constructing a transformed eukaryotic microorganism for the production of a heterologous polypeptide wherein the host comprises an inactive Yap3 protease which prevents the degradation of the heterologously produced protein (see entire document, especially column 19, claim 1; column 20, claim 11; as well as columns 10-12, Examples 6-10). Egel-Matani et al teach such a method wherein the eukaryotic host microorganism is *S. pombe* (see, e.g., column 4, lines 7-12; and column 20, claim 11). Egel-Matani et al further teach that inactivation of Yap3 results in 2-fold higher production of the polypeptide than would occur in yeast with wild-type levels of Yap3 protease activity (column 19, claim 1). Egel-Matani et al also teach the collection/isolation of the heterologous protein (*ibid*). Therefore, based on the teachings of Egel-Matani, there would be a reasonable expectation of success that their disclosed method would work for other *S. pombe* proteases.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14 and 20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of copending Application No. 12/025,138.

Claims 14 and 20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 5 of copending Application No. 12/025,138 in view of [www.genedb.org/genedb/pombe/](http://www.genedb.org/genedb/pombe/), and in further view of Hombergh et al.

Applicants request that these rejections be held in abeyance.

***Allowable Subject Matter***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

Michele K Joike  
Examiner  
Art Unit 1636